



WEEK ENDING AUGUST 29, 2014

OPP Weekly Activity Report

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ACROSS OPP

OPP Supports FEDS FEED FAMILIES. In support of this important annual campaign, every Division and the IO in OPP stepped up to the plate to do its share -- with canned goods/non-perishable items collected at multiple events throughout the last few months, providing coffee/pastry, pizza, smoothies, baked goods, movies, iced tea, supermarket sweeps, etc. There were inter-divisional competitions as well as a joint baked goods for canned goods event with OSWER's Office of Underground Storage Tanks. While the total pounds have not yet been tallied, OPP clearly made a large and impressive contribution to this worthy cause.

HEALTH EFFECTS DIVISION

Conference Call with OSHA and OMB on Process to Update PELs: HED and FEAD staff participated in a conference call with OSHA and OMB related to the OSHA effort to update their Permissible Exposure Limits (PELs). OSHA is reviewing its overall approach to managing chemical exposures and is seeking stakeholder input through a Request for Information (RFI). OPP had provided comments about 6 weeks ago on their draft document and the discussion centered around those comments which OSHA essentially incorporated into their revised RFI. The key topics of discussion included use of epidemiology in risk assessment, consideration of non-cancer endpoints, general approaches to use of animal data, mode of action, and exposure metrics. The key action item is that OSHA will visit OPP (date yet to be determined) to discuss pesticide risk assessment processes in more detail. (Jeff Dawson, 305-7329)

HED Completes Protocol Review of a Special Neurotoxicity Study for Sulfuryl Fluoride: Based on available data for sulfuryl fluoride (SF), HED identified a residual uncertainty regarding the potential impact of SF exposure during the perinatal period. The Agency recommended that the registrant, Dow AgroSciences (DAS), conduct a special neurotoxicity study instead of a guideline developmental neurotoxicity study. Members of HED met to review a protocol developed by DAS to address the residual uncertainty. HED concluded that the protocol appears to be adequate to address the data gap and provided specific comments to DAS addressing minor concerns. (Jess Rowland, 308-2719; Anna Lowit, 308-4135; Elizabeth Mendez, 305-5453; Jaime D'Agostino, 347-0403)

Meeting to Discuss Kidney Effects in Oral and Dermal Studies with Picaridin: Representatives from the Health Effects Division (HED), Pesticide Re-Evaluation Division (PRD) and Registration Division (RD) met (via teleconference) with the Registrant for picaridin to discuss kidney effects observed in dermal and oral toxicity studies. In the studies, the kidney effects observed in the rat seem to be a result of alpha2u-globulin (a2u-g) accumulation, which is not relevant to humans for risk assessment. Therefore, HED suggested immunohistochemical staining be

done to confirm the presence of renal alpha2u-globulin. If the kidney effects are a result of alpha2u-globulin (a2u-g) accumulation, HED may conduct a qualitative, rather than quantitative, risk assessment for picaridin. (Karlyn Middleton, 308-0004)

PESTICIDE RE-EVALUATION DIVISION

Cyfluthrins Draft Risk Assessment (DRA) Kick-off Meeting. On August 18, 2014, PRD met with the cyfluthrins registration review team members from EFED, HED, BEAD and RD to discuss the current status of the chemical, proposed timeline for completing the DRA, and next steps. The majority of the data called-in for registration review has been received. Cyfluthrin and beta-cyfluthrin are pyrethroid insecticides registered for use on a variety of agricultural use sites as well as on residential indoor/outdoor areas, turf/ornamentals, pets/pet houses, poultry processing plant premises, recreational/golf areas, tobacco, and for use as an outdoor wood protection treatment. The PRD/EFED effort to coordinate and streamline the pyrethroid risk assessments as a group in order to reduce workloads and accelerate mitigation was also discussed. The team will meet again after a strategy for conducting the pyrethroid assessments is further developed, later this fall. (Garland Waleko, 703-308-8049)

EPA Meets with Clethodim Registrants to Discuss Label Clarifications Following the Preliminary Risk Assessments. On August 26, 2014, staff from PRD, HED, and EFED met with clethodim technical registrants (including Valent, Arysta, Albaugh, ADAMA, Amtide, Tacoma, Willowood, Rotam, Redeagle, and Nisso BASF) to discuss label clarifications and moving forward through the registration review process. The technical registrants agreed to provide EPA with information on application rates and intervals that were missing from clethodim labels in order to refine some of the assumptions made in the preliminary risk assessment. The registrants expressed their desire to see EPA implement a mechanism for ensuring that label clarifications made by technical registrants are likewise adopted by all product registrants. The clethodim registrants offered to work collaboratively with the EPA to identify options to define this process. Clethodim is a post-emergent selective herbicide used on a wide range of crop and non-crop areas to control a variety of grasses. The preliminary risk assessments for clethodim were published for a 60-day comment period in March 2014, and a proposed interim decision for registration review is expected in 2015. (Ricardo Jones, 703-347-0493)

FIELD & EXTERNAL AFFAIRS DIVISION

FEAD on Regulator Panel at ASPCRO 58th Annual Meeting. The Association of Structural Pest Control Regulatory Officials invited EPA, OSHA, NPMA and CA-DPR to hold a panel discussion on August 25 about meeting pesticide labeling requirements to provide consistent hazard information when pesticide products

are accompanied by OSHA's GHS-aligned Safety Data Sheets. OSHA's representative discussed its implementation of the Globally Harmonized System of Classification and Labeling of Chemicals in early 2012 by revising its Hazard Communication regulations. FEAD, representing EPA at the panel, underlined the fact that EPA has not amended pesticide labeling regulations to reflect the GHS. FEAD explained that there are differences in the classification criteria, hazard statements, pictograms and signal words between EPA's current requirements and the GHS. EPA gave an overview of the guidance document, PR Notice 2012-1, which was published in April 2012 to aid registrants in reconciling hazard communication on SDSs with their associated FIFRA labels, minimizing risk to workers who may find the two sets of information confusing. The panelists' clarifications and answers to Q&A were well received and highlighted the need for continued outreach on the topic. (Martha Shimkin, 305-5160; Lily Negash, 347-8515)

National Potato Council Summer Tour. FEAD coordinated another successful crop tour held August 26-27. On the first day, 19 OPP participants travelled to Southern New Jersey to visit Jim Coombs Farm, Seabrook Brother's and Sons Packing Facility, and Rutgers Research Farm. Participants observed a demonstration of an aerial pesticide application at the Coombs Farm and later heard an overview of agricultural issues from New Jersey's Secretary of Agriculture at Rutgers Research Farm. On the second day, participants toured the Herr's Potato Chip Plant and Herr's Beef Cattle Operation. The Herr's Potato Chip Plant promotes sustainability in that the majority of their unusable potato and corn scraps are fed to their cattle. (Amaris Johnson, 305-9542; Joe Hogue, 308-9072)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

OPP FOIA Request Status Report for Aug 18- 22, 2014							
Requests Received		Requests Closed			Requests Open		
FY14	This Week	FY14	FYTD	This Week	FY14	Prior Years	Total
441	10	296	395	12	145	251	396

(Ana Espinoza, 703-347-0102)

OPPIN 5.3 PRIA enhancements completed ITRMD/SDDDB has completed development and testing for electronic label review, 45/90 day review, and discretionary refund enhancements for the OPPIN database. The code has been delivered to EzTech for deployment. OEI has three weeks to complete this task. (Patrick Dobak 308-8180 and Price Wood 305-5066)

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

BPPD Registers New Biochemical Active Ingredient. On August 26, BPPD registered a new active ingredient, (E,E)-1-(1-oxo-2,4-decadienyl) pyrrolidine also known as sarmentine. This biochemical pesticide is for use as an herbicide to control grasses and broadleaf weeds on non-food crops in agricultural, residential, and other areas such as golf courses and parks. It is a naturally occurring constituent of peppercorns that has been extracted from fruit, foliage and roots of a variety of pepper plants. Although the specific mode of action of sarmentine is not completely understood, it is believed that the substance damages and degrades the integrity of plant cell walls. The pesticide products are MBI-011 TGAI (EPA Reg. No. 84059-19) and MBI-011 EP (EPA Reg. No. 84059-20). More information on this new active ingredient can be accessed by viewing docket no. HQ-EPA-OPP-2014-0003. (Leonard Cole, 305-5412)

New Biochemical AI Registered for Fungicide/Bactericide Treatment. On August 29, BPPD registered a new active ingredient, tea tree oil. This biochemical pesticide is for use as a fungicide/bactericide on the following food commodities: leafy vegetables (group 4), fruiting vegetables (group 8), cucurbit vegetables (group 9), berries (group 13), tree nuts (group 14), cereal grains (group 15), avocado, banana, mango, papaya, passion fruit, plantain, and peanuts. Based on data and information submitted, EPA has made a non-food use determination for these commodities. Tea tree oil is extracted from the leaves and terminal branches of the tea tree (*Melaleuca alternifolia*) which is a member of the plant family Myrtaceae and is indigenous to Australia, New Zealand, and Southeast Asia. Tea tree oil has antifungal properties and is effective against a broad spectrum of plant-pathogenic fungi. It has been shown to affect cell respiration and alter the cell membrane structure in yeast. The pesticide products are the manufacturing-use product (MP), Tea Tree Oil Technical (EPA Reg. No. 86182-2) and the end-use product (EP), Timorex Gold (EPA Reg. No. 86182-1). More information on this new active ingredient can be accessed by viewing docket no. HQ-EPA-OPP-2009-0440. (Colin G. Walsh, 308-0298)

BPPD Discusses Risk Assessment with Chinese Food Safety Regulators. On August 20th, 5 members of the Chinese National Safety Commission of Agriculturally Modified Organisms visited BPPD for a presentation and discussion on risk assessment procedures for food and feed products derived from agricultural biotechnology. The scientists are professors at universities and members of the

Chinese Academy of Agricultural Sciences, with ongoing research programs into the assessment of toxicity and allergenicity potential of various ag biotech products. Currently, China has approved commercial production of the following biotech crops: Insect resistant cotton and poplar; virus resistant papaya, sweet pepper and tomato. While significant research continues on genetically engineered rice, maize and other staple crops, biosafety certificates allowing full commercial use have not yet been issued. The group was hosted by the US Grains Council. (John Kough, 308-8267; Chris Wozniak, 308-4043).

BPPD Attends 31st-Annual Mid-Atlantic Plant Molecular Biology Society Meeting.

From August 21 – 22, Chris Wozniak and Kenneth Haymes attended the Mid-Atlantic Plant Molecular Biology Society (MAPMBS) at the National Wildlife Visitor Center, Patuxent Wildlife Refuge in Laurel, MD. Organized symposia included sessions on: genomic resources, synthetic biology and regulated growth and development in plants. Some side-bar conversations centered on regulations of transgenic plants and field studies. Questions were raised about gene silencing and whether regulatory agencies are working together towards a faster approval process and the need to have better outreach to universities to ensure university scientists have a better concept of how policy and regulations affect them. (Chris Wozniak, 308-4043; and Kenneth M. Haymes, 347-0398)

BPPD Staff Teach Biotech to Foreign Students in Regulatory Course. From August 11 to 15, 22 students from eleven countries, mostly in SE Asia and Latin America, attended a regulatory course at the University of Missouri in Columbia, MO focused on products of biotechnology. The Biotechnology Regulatory Immersion course has been held at the university for several years and is intended to aid countries developing regulatory systems for agricultural products derived from recombinant DNA technology, including plants, animals and microbes. In addition to regulatory discussions and lectures, the students also participated in some laboratory exercises regarding transformation of plant tissues with transgenic markers. University researchers and extension personnel provided insight into their experiences with the US and European systems of regulation as well as basic fundamentals of risk assessment. (Chris Wozniak, 308-4043)

ENVIRONMENTAL FATE & EFFECTS DIVISION

Collaboration with U.S Fish and Wildlife Service (FWS) Hawaii Field Office to Obtain Listed Species Range Information. On August 28, EFED and PRD staff participated in a webinar meeting with FWS Headquarters, the FWS Hawaii Field Office, and the Federal Endangered Species Task Force (FESTF) group. The purpose of this webinar was to initiate dialogue regarding a collaborative effort between FESTF and the FWS Hawaii Field Office to share existing geospatial data on listed species that occur in the Hawaiian Islands, including over 400 listed plant species. The

ultimate goal of this effort is to develop and share FWS-vetted range maps for listed species that occur only on the Hawaiian Islands for use in future pesticide consultations with the Services. (Anita Pease, 703-305-0392 and Cathy Eiden, 703-305-7887).

Honey Bee Health Coalition Webinars. On August 22, 2014, EFED staff participated in a series of webinars for the Honey Bee Health Coalition. In the first webinar, Dr. Dennis vanEngelsdorp (University of Maryland) provided an overview of Bee Informed Partnership efforts to develop honey bee technical teams as a means of disseminating information to beekeepers on maintaining hive health. Currently there are technology transfer teams in California, Minnesota, Oregon, Florida and Hawaii, and the Partnership hopes to expand to other areas of the country. A second webinar presented by the Florida Fruit and Vegetable Association focused on challenges facing citrus growers relative to citrus greening, a bacterial disease vectored by the Asian psyllid. The speaker provided an overview of the Florida Pollinator Management Plan, which is intended to enhance communication/cooperation between growers/applicators and beekeepers toward protecting managed bees while ensuring a sustainable citrus industry. (Tom Steeger, 703-305-5444).

Corn Dust Research Consortium. On August 27, 2014, EFED staff participated in a meeting of the Corn Dust Research Consortium Advisory Committee. The committee had an opportunity to review the 2014 mid-term report on research directed toward understanding and reducing honey bee exposure to dust emitted during the planting of treated corn seed. The research is being conducted by independent teams at the University of Guelph, Ohio State University, Iowa State University, and Bee Alert Technologies, Inc. This is the second year of studies examining the efficacy of dust reduction technologies and examining the extent to which abraded seed coating dust may represent an exposure pathway for bees. The CDRC is coordinated by the Pollinator Partnership. (Tom Steeger, 703-305-5444).

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

Response to CDC on Occupational Exposure Under Select Agent Program. CDC requested additional information on the laboratory's response to an occupational exposure to *Bacillus anthracis* as part of the laboratory's Select Agent documentation. The laboratory worked with the Environmental Science Center Safety, Health and Environmental Manager to develop a process for seeking medical treatment, reporting exposure, and conducting follow up risk management review. The language will be included in the biosafety plan for the Select Agent activities. The draft section was provided to CDC for review. (Susan Lawrence, 410-305-2954 and Michele Cottrill, 410-305-2955)

Decision Memorandum for Interagency Agreement with Department of Homeland Security Drafted

The Department of Homeland Security (DHS) Science and Technology Directorate and USDA's Animal and Plant Health Inspection Service have an urgent need for disinfectant product efficacy data for treating porous surfaces contaminated with high consequence foreign animal diseases. DHS has requested technical assistance from EPA to develop standard efficacy methods and associated laboratory data. Using FY 2014 DHS funds, an Interagency Agreement with EPA is under development. The budget (approximately \$420K over a two year period) is designed to offset costs of conducting the laboratory assays and to provide resources for laboratory personnel. MLB has drafted the Decision Memorandum (DM) within the Integrated Grants Management System (IGMS); the DM is under internal review. The next step is to prepare a Commitment Notice. (Stephen Tomasino, 410 305-2976)

REGISTRATION DIVISION

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date
The Fungicide Branch granted:					
Copper sulfate pentahydrate	Delta AgroChemicals	88633-3	R301	9/2/2014	8/26/2014
Lindsay Roe, 703/347-0506					
Potassium 1-naphthaleneacetate	Amvac Chemical	5481-580	R301	9/8/2014	8/26/2014
Tony Kish, 703/308-9443					
The Herbicide Branch granted:					
Glyphosate-isopropylammonium	The Scotts Company	239-2723 239-2724	R300	9/9/2014	8/26/2014
Sarah Meadows, 703/347-0505					
Flumioxazin	Makhteshim Agan of North America, Inc.	66222-258	R314	9/10/2014	8/26/2014
Bethany Benbow, 703/347-8072					
Imazamox	BASF Corporation	241-441	R350	9/11/2014	8/27/2014
Bromoxynil octanoate	Bayer CropScience LP	264-442	R351	10/6/2014	8/26/2014
Orthosulfamuron	Isagro S.P.A.	71711-43	R351	9/23/2014	8/27/2014
Glyphosate	Agsaver II, LLC	85806-1	R351	9/23/2014	8/27/2014
Maggie Rudick, 703/347-0257					
Amicarbazone	Arysta LifeScience North America, LLC	66330-45	R351	9/15/2014	8/27/2014
Emily Schmid, 703/347-0182					

The Insecticide Branch granted:					
Cypermethrin	Chemsico	9688-320	R310	9/1/2014	8/27/2014
Linda DeLuise, 703/305-5428					
Fipronil	Gharda Generics, Inc.	84836-18	R310	8/29/2014	8/26/2014
MGK 264	McLaughlin Gormley King Company	1021-2569 1021-2570 1021-97	R340	8/30/2014	8/27/2014
Carmen Rodia, 703/306-0327					
Bifenthrin	FMC Corporation Agricultural Products Group	279-3055	R351	9/22/2014	8/27/2014
BeWanda Alexander, 703/305-7060					
The Insecticide-Rodenticide Branch granted:					
Imidacloprid	Albaugh, LLC	42750-267 42750-268	R314	9/3/2014	8/26/2014
Jennifer Urbanski, 703/347-0156					
Emamectin benzoate	Rotam Limited	81598-11	R334	9/2/2014	8/26/2014
Jessica Rogala, 703/347-0263					
Potassium laurate	Miracle Gro Lawns Products, Inc.	62355-3	R340	8/25/2014	8/25/2014
Gene Benbow, 703/308-0235					
PRIA Categories					
<p>R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix (3) (4); R301 – New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner (2) (3); R310 – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging (2) (3); R314 – New end use product containing two or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging (2) (3); R334 – New product; MUP or End use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation (2) (3); R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements) (2) (3); and R351 – Amendment adding a new unregistered source of active ingredient (2) (3).</p>					